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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,041	02/09/2001	Ronald Klein	UF-10293	8442

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EXAMINER	
BAKER, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 07/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/780,041	Applicant(s) KLEIN ET AL.	
	Examiner Anne-Marie Baker	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed June 25, 2001 (Paper No. 2) has been entered.

Claims 1-22 are pending in the instant application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 11, and 15-19, drawn to a method for producing a non-human animal model by transferring a gene encoding an aberrant form of tau, using somatic gene transfer techniques, a non-human animal comprising in its somatic cells a gene encoding an aberrant form of tau, and a method for inducing behavioral changes by somatic administration of a gene encoding an aberrant form of tau, classified in class 800, subclass 8.

II. Claims 1-3, 6, 7, 11, 15-17, 20, and 21, drawn to a method for producing a non-human animal model by transferring a gene encoding an aberrant form of alpha-synuclein, using somatic gene transfer techniques, a non-human animal comprising in its somatic cells a gene encoding an aberrant form of alpha-synuclein in somatic cells, and a method for inducing behavioral changes by somatic administration of a gene encoding an aberrant form of alpha-synuclein, classified in class 800, subclass 8.

III. Claims 1-3, 8, 11, 15-17, and 22, drawn to a method for producing a non-human animal model by transferring a gene encoding a mutant amyloid precursor protein (APP), using somatic gene transfer techniques, a non-human animal comprising in its somatic cells a gene encoding a mutant amyloid precursor protein, and a method for inducing behavioral

changes by somatic administration of a gene encoding a mutant amyloid precursor protein classified in class 800, subclass 8.

IV. Claims 1-3, 8, 11, 15-17, and 22, drawn to a method for producing a non-human animal model by transferring a gene encoding a mutant presenilin-1 (PS1), using somatic gene transfer techniques, a non-human animal comprising in its somatic cells a gene encoding a mutant presenilin-1, and a method for inducing behavioral changes by somatic administration of a gene encoding a mutant presenilin-1, classified in class 800, subclass 8.

V. Claims 9 and 10, drawn to a method for identifying a combination of genes relevant to a particular human pathology, classified in class 514, subclass 44.

VI. Claim 12, drawn to a pharmaceutical, classified in class 514, subclass 1.

VII. Claims 13 and 14, drawn to a method for inducing neurofibrillary tangles in the brain of a non-human animal by injecting into the brain a gene expression construct encoding tau and a non-human animal produced by injecting into the brain a gene expression construct encoding tau, classified in class 800, subclass 8.

VIII. Claims 13 and 14, drawn to a method for inducing neurofibrillary tangles in the brain of a non-human animal by injecting into the brain a gene expression construct encoding alpha-synuclein and a non-human animal produced by injecting into the brain a gene expression construct encoding alpha-synuclein, classified in class 800, subclass 8.

IX. Claims 13 and 14, drawn to a method for inducing neurofibrillary tangles in the brain of a non-human animal by injecting into the brain a gene expression construct encoding presenilin-1 and a non-human animal produced by injecting into the brain a gene expression construct encoding presenilin-1, classified in class 800, subclass 8.

X. Claims 13 and 14, drawn to a method for inducing neurofibrillary tangles in the brain of a non-human animal by injecting into the brain a gene expression construct encoding

amyloid precursor protein and a non-human animal produced by injecting into the brain a gene expression construct encoding amyloid precursor protein, classified in class 800, subclass 8.

XI. Claims 13 and 14, drawn to a method for inducing neurofibrillary tangles in the brain of a non-human animal by injecting into the brain a gene expression construct encoding amyloid precursor protein and a non-human animal produced by injecting into the brain a gene expression construct encoding amyloid precursor protein, classified in class 800, subclass 8.

XII. Claims 13 and 14, drawn to a method for inducing neurofibrillary tangles in the brain of a non-human animal by injecting into the brain a gene expression construct encoding IL-6 and a non-human animal produced by injecting into the brain a gene expression construct encoding IL-6, classified in class 800, subclass 8.

Claims 1-3, 11, and 15-17 embrace the inventions of Groups I-IV. Should any one of Groups I-IV be elected, Claims 1-3, 11, and 15-17 will be examined only to the extent that they encompass the elected subject matter.

Claim 8 embraces the inventions of Groups III and IV. Should either of Groups III or IV be elected, Claim 8 will be examined only to the extent that it encompasses the elected subject matter.

Claims 13 and 14 embrace the inventions of Groups VII-XII. Should any one of Groups VII-XII be elected, Claims 13 and 14 will be examined only to the extent that they encompass the elected subject matter.

Claim 22 embraces the inventions of Groups III and IV. Should either of Groups III or IV be elected, Claim 22 will be examined only to the extent that it encompasses the elected subject matter.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV and VII-XII are patentably distinct, one from the other, because the inventions are drawn to distinct compositions and materially different methods. Animals having different genetic modifications constitute distinct inventions. The animals are not obvious variants, one over the other. The genetically modified animals of the invention of Group I are structurally, chemically, biologically, and functionally distinct from the genetically modified animals of the inventions of Groups II-IV and VII-XII. Furthermore, the methods of the inventions of Groups I-IV and VII-XII are patentably distinct, one from the other, because the methods require different starting materials (i.e., different genes), different modes of operation, and produce different effects. Thus, the compositions and methods of the inventions of Groups I-IV and VII-XII are patentably distinct, one from the other.

Invention V is patentably distinct from inventions I-IV and VI-XII because the inventions are drawn to materially different methods. The method of the invention of Group V is directed to identifying a combination of genes relevant to a particular human pathology, whereas the methods of the inventions of Groups I-IV and VI-XII are directed to producing non-human animal models. The methods require different starting materials, different modes of operation, and produce different effects. Furthermore, the pharmaceutical composition of the invention of Group VI is not required for and cannot be used in the method of the invention of Group V. Thus, the method of the invention of Group V is patentably distinct from the methods and compositions of the inventions of Groups I-IV and VI-XII, and vice versa.

Invention VI is patentably distinct from inventions I-V and VII-XII because the invention of Group VI is drawn to a distinct composition that is not required for and cannot be used in the methods of the inventions of Groups I-V and VII-XII. Furthermore, the pharmaceutical composition is clearly structurally, chemically, biologically, and functionally distinct from the animals of the inventions of Groups I-IV and VII-XII. Thus, the composition of the invention of Group VI is patentably distinct from the compositions and methods of the inventions of Groups I-V and VII-XII, and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Anne-Marie Baker, Ph.D.

Anne-Marie Baker
ANNE-MARIE BAKER
PATENT EXAMINER